DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 2 1999

1457 '99 SEP -8 A10:03

Thomas A. Gerding
Director, Regulatory Affairs
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Re: Docket No. 99P-0389/CP1

Dear Mr. Gerding:

I am writing to inform you that the Food and Drug Administration has not resolved the issues raised in your petition submitted on March 3, 1999. Your petition requests that FDA not approve abbreviated new drug applications for topical dermatological drug products based on the principles outlined for establishing bioequivalence (specifically dermatopharmacokinetic studies) proposed in a draft guidance for industry on the products. You claim that if your request is granted, the FDA should withdraw the draft guidance entitled "Topical Dermatological Drug Product NDA's and ANDA's -- In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies" and published in the June 18, 1999 Federal Register.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-0389

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